

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

JAN 08 2014

Ans

DEPUTY CLERK

UNITED STATES OF AMERICA)
v.) No. 3:14-00007
EDWARD MANOOKIAN) 18 U.S.C. § 371
a/k/a Ed Manning) 21 U.S.C. § 331(d)
BRIAN MANOOKIAN) 18 U.S.C. § 1341
a/k/a Brian Manning) 18 U.S.C. § 2
KAREN MANOOKIAN)
a/k/a Karen Phillips)

INDICTMENT

COUNT ONE

THE GRAND JURY CHARGES:

At all times material to this Indictment:

Background

1. Melanocorp, Inc. ("Melanocorp") was a for-profit corporation that conducted operations in Hendersonville, Tennessee and Brentwood, Tennessee, and that used an office address in Nashville, Tennessee.
 2. Melanocorp operated the internet website www.melanocorp.com.
 3. Melanocorp also did business as Manning & Associates, Inc.
 4. Defendant **EDWARD MANOOKIAN**, also known as Ed Manning, was owner and registered agent of Melanocorp and was actively engaged in business activities on behalf of Melanocorp.

5. Defendant **BRIAN MANOOKIAN**, also known as Brian Manning, was Assistant Director of Sales & Marketing of Melanocorp and was actively engaged in business activities on behalf of Melanocorp.

6. Defendant **KAREN MANOOKIAN** was Director of Customer Service of Melanocorp and was actively engaged in business activities on behalf of Melanocorp.

7. An individual known to the Grand Jury with the initials "C.R." was an employee of Melanocorp.

U.S. Food, Drug, and Cosmetic Act

8. The term "drug" is defined by the Food Drug and Cosmetic Act, Title 21, United States Code, Section 301, et seq. (the "FDCA"), to include any articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and any articles (other than food) intended to affect the structure of any function of the body of man or other animals. Title 21, United States Code, Section 321(g).

9. Pursuant to the FDCA, a new drug is one that "is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof" Title 21, United States Code, Section 321(p).

10. Pursuant to the FDCA, the term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. Title 21, United States Code, Section 321(m). Promotional material on a website or written promotional correspondence can constitute labeling.

11. Pursuant to the FDCA, shipment of a product between one state and another state, or between the United States and a foreign country, for commercial reasons qualifies as interstate

commerce. Title 21, United States Code, Section 321(b) (defining “interstate commerce” to mean “commerce between any State or Territory and any place outside thereof”).

12. Pursuant to the FDCA, a drug is “misbranded” if, among other things, its labeling is false or misleading in any particular. Title 21, United States Code, Sections 352(a).

13. Pursuant to the FDCA, a drug is also deemed “misbranded” if its labeling fails to bear adequate directions for use. Title 21, United States Code, Sections 352(f).

14. Pursuant to the FDCA, it is unlawful to introduce an unapproved new drug into interstate commerce. Title 21, United States Code, Section 331(d).

15. Pursuant to the FDCA, it is unlawful to introduce a misbranded drug into interstate commerce. Title 21, United States Code, Section 331(a).

Smuggling Goods from the United States

16. Pursuant to Title 18, United States Code, Section 554, it is unlawful to export or send from the United States, or to attempt to export or send from the United States, any merchandise, article, or object, where that exportation was or would have been contrary to any law or regulation of the United States while knowing that the exporting or sending of these items was contrary to any law or regulation of the United States and doing so fraudulently or knowingly.

Melanotan II

17. Melanotan II (also known as “MII” or “MT2”) was a peptide, or series of amino acids, that was marketed, sold, and shipped by Melanocorp to customers in the United States and abroad.

18. Melanocorp, through the internet website www.melanocorp.com, advertised MII as an injectable tanning product with additional claims that it was effective in protecting against skin cancer and rosacea (a flushing and redness of the skin).

19. Melanocorp advertised the MII it offered for sale as being 100% manufactured in the United States.

20. The U.S. Food and Drug Administration (“FDA”) determined that MII was a new drug because it was not generally recognized by qualified experts as safe and effective for its labeled uses.

21. The FDA did not approve MII for use, and hence MII was classified as an unapproved new drug.

22. The labeling of the MII distributed by Melanocorp was false and misleading, and lacked adequate directions for its intended uses, and hence MII was a misbranded drug.

Correspondence between FDA and Melanocorp

23. On or about August 30, 2007, defendant **BRIAN MANOOKIAN** received a warning letter from an FDA District Director expressing concern about Melanocorp’s marketing of MII. The Warning Letter referenced FDA objection to certain statements on the Melanocorp website that documented the intended uses of MII. The Warning Letter stated that, based on this information and the statements on the Melanocorp website, MII constituted a “new drug” under the FDCA that could not be introduced or delivered for introduction into interstate commerce without an FDA-approved application. The Warning Letter concluded that the sale of MII by defendant **BRIAN MANOOKIAN** without an FDA-approved application violated the FDCA and instructed defendant Brian Manookian to take prompt action to correct the violations cited in the Warning Letter.

24. On or about September 17, 2007, defendant **EDWARD MANOOKIAN**, writing as President of Melanocorp, responded to the FDA's Warning Letter dated August 30, 2007. In the letter, defendant **EDWARD MANOOKIAN** stated that Melanocorp had stopped all promotion and sale of MII in the United States and had stopped taking orders for MII from U.S. residents. Defendant **EDWARD MANOOKIAN** also stated that Melanocorp intended to re-establish its website for individuals outside the United States, and stated that Melanocorp would not accept orders for MII from any individual with a U.S. mailing address.

25. On or about November 29, 2007, the FDA sent a letter to an attorney representing defendant **EDWARD MANOOKIAN** which stated that his response dated September 17, 2007 was inadequate in many areas. This letter reiterated that MII was considered by FDA to be an unapproved drug and warned that its introduction or delivery for introduction into interstate commerce would be a violation of the FDCA. The letter specifically stated that defendant **EDWARD MANOOKIAN'S** pronounced commitment to sell Melanotan II outside the United States violated the FDCA. The letter also stated that it was the responsibility of defendant **EDWARD MANOOKIAN** to assure that the products he distributed complied with all requirements of federal law and FDA regulations.

26. On or about December 14, 2007, an attorney for defendant **EDWARD MANOOKIAN** sent a letter to the FDA indicating that Melanocorp acknowledged that FDA considered MII to be an unapproved new drug and that FDA had requested that Melanocorp not distribute or market MII in the United States. The attorney confirmed that Melanocorp had stopped taking orders for MII from U.S. residents and cited actions that Melanocorp would take to "further clarify that the product is not intended for U.S. customers." In this letter, the attorney also opined that the FDCA permitted drugs that may not be sold or distributed in the United

States to be exported under certain circumstances, and suggested that Melanocorp could export MII in compliance with the FDCA.

27. On or about December 28, 2007, in response to this letter, the FDA sent a letter to the attorney for defendant **EDWARD MANOOKIAN** reiterating reiterated that “unapproved new drugs [did] not qualify for export ” and extending an invitation to the attorney to meet with FDA staff so the FDA could assist in resolving Melanocorp’s lack of compliance with Federal regulations.

Conspiracy

28. Beginning on or about September 1, 2007 and continuing until in or around April 2009, in the Middle District of Tennessee and elsewhere, defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, AND KAREN MANOOKIAN** did knowingly and willfully combine, conspire, confederate, and agree with each other, and with others known and unknown to the Grand Jury, to commit offenses against the United States, that is:

- a) To introduce and deliver for introduction into interstate commerce an unapproved new drug, and to cause an unapproved new drug to be introduced and delivered for introduction into interstate commerce, with intent to defraud and mislead, in violation of Title 21, United States Code, Sections 331(d), 333(a)(2), and 355;
- b) To introduce and deliver for introduction into interstate commerce a misbranded drug, and to cause a misbranded drug to be introduced and delivered for introduction into interstate commerce, which drug lacked adequate directions for use and featured false and misleading labeling, with

intent to defraud and mislead, in violation of Title 21, United States Code, Sections 331(a), 333(a)(2), and 352(a) and (f); and

- c) To fraudulently and knowingly export and send from the United States, and attempt to export and send from the United States, merchandise, articles and objects, contrary to any law or regulation of the United States, to wit: the export of unapproved new drugs and misbranded drugs, in violation of Title 18, United States Code, Section 554(a).

Objects of the Conspiracy

29. The objects of the conspiracy were to obtain and distribute MII; to market and sell MII; to transfer and control the revenues and profits arising from the sale of MII; to conceal prohibited activities from detection by the United States Government and other governments so as to avoid penalties and disruption of the illegal activity; and to illegally enrich defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, AND KAREN MANOOKIAN** by unlawfully introducing misbranded and unapproved new drugs into interstate commerce.

Manner and Means

30. The manner and means by which the defendants and their conspirators sought to accomplish the objects of the conspiracy included, among others, the following:

- a) To obtain MII for distribution to customers of Melanocorp;
- b) To market and accept orders for MII via Melanocorp and its website, www.melanocorp.com;
- c) To charge and receive money from customers in exchange for providing MII;
- d) To misrepresent the contents and value of the MII on shipping documents;
- e) To misrepresent the source and quality of MII sold by Melanocorp;

- f) To misrepresent to FDA that Melanocorp would not distribute MII within the United States and would not take orders for MII from residents of the United States;
- g) To distribute MII to customers of Melanocorp, thereby introducing MII into interstate commerce; and
- h) To export MII in violation of the laws and regulations of the United States.

Overt Acts

31. In furtherance of this conspiracy, and to accomplish its purposes and objects, defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, KAREN MANOOKIAN**, and other conspirators known and unknown to the Grand Jury committed and caused to be committed, in the Middle District of Tennessee, and elsewhere, at least one of the following overt acts, among others:

- a) On or about February 8, 2008, defendant **KAREN MANOOKIAN** caused vials of MII to be unlawfully shipped and delivered via Federal Express to an address located outside of the United States in Dublin, Ireland. The shipping documents relating to said vials fraudulently described the contents of the vials as being cosmetic tanning supplies for personal use with a declared value of \$10.00.
- b) On or about March 13, 2008, defendant **KAREN MANOOKIAN** caused vials of MII to be unlawfully shipped and delivered via United States Postal Service Express Mail to an address located outside of the United States in Dublin, Ireland. The shipping documents relating to said vials fraudulently

described the contents of the vials as being silicon dioxide derivative for personal use with a declared value of \$10.00.

- c) On or about July 3, 2008, defendant **KAREN MANOOKIAN** caused \$1,225.00 to be charged to a credit card belonging to a customer in Allison Park, Pennsylvania in exchange for the sale of MII.
- d) On or about July 17, 2008, defendants **EDWARD MANOOKIAN** and **KAREN MANOOKIAN** caused a package containing MII to be sent to an address in Allison Park, Pennsylvania via the United States Postal Service in fulfilment of a customer order.
- e) On or about November 18, 2008, defendant **KAREN MANOOKIAN** caused vials of MII to be unlawfully shipped and delivered via United Parcel Service to an address located outside of the United States in Dublin, Ireland. The shipping label relating to said vials fraudulently described the contents of the package as amino acids for research use.
- f) On or about December 2, 2008, defendant **EDWARD MANOOKIAN** knowingly and fraudulently caused the importation of approximately 500 vials of MII addressed to Ed Manning of Manning and Associates, Inc. in Hendersonville, Tennessee from Dr. Hongyan Xu, GL BioChem (Shanghai) Ltd. in Shanghai, China. Said shipment was declared as "peptide sample for research use only" with a declared value of \$10.00.
- g) On or about January 14, 2009, defendants **KAREN MANOOKIAN** and **EDWARD MANOOKIAN** caused vials of MII to be unlawfully shipped and delivered via United Parcel Service to an address located outside of the United

States in Perth, Australia. The shipping documents relating to said vials provided a declared value of \$10.00.

- h) On or about January 29, 2009, defendant **KAREN MANOOKIAN** caused vials of MII to be unlawfully shipped and delivered via United Parcel Service to an address located outside of the United States in Glasgow, United Kingdom. The shipping documents relating to said vials fraudulently described the contents of the vials as being silicon dioxide derivative with a declared value of \$10.00.
- i) On or about February 9, 2009, defendants **EDWARD MANOOKIAN** and **KAREN MANOOKIAN** caused a package containing MII to be sent to an address in Long Beach, California via United Parcel Service in fulfilment of a customer order.
- j) On or about February 19, 2009, defendant **KAREN MANOOKIAN** caused vials of MII to be unlawfully shipped and delivered via United Parcel Service to an address located outside of the United States in Lower Templestowe, Australia. The shipping documents relating to said vials provided a declared value of \$10.00.
- k) Between on or about March 9, 2009 and on or about April 22, 2009, defendant **EDWARD MANOOKIAN** exchanged emails with GL Biochem (Shanghai) Ltd. seeking the order, shipment, and importation of MII.
- l) On or about March 18, 2009, defendant **EDWARD MANOOKIAN** caused a wire transfer of \$5,830.00 to be sent from a Bank of America account in the

name of Manning Associates, Inc, d/b/a Melanocorp, Inc., to an account in the name of GL Biochen.

- m) On or about March 30, 2009, defendant **KAREN MANOOKIAN** caused vials of MII to be unlawfully shipped and delivered via Federal Express to an address located outside of the United States in Alicante, Spain. The shipping label relating to said vials fraudulently described the contents of the package as "cosmetic skincare products" with a declared value of \$10.00.
- n) On or about April 3, 2009, defendant **KAREN MANOOKIAN** caused vials of MII to be unlawfully shipped and delivered via United Parcel Service to an address located outside of the United States in Athens, Greece. The shipping documents relating to said vials provided a declared value of \$10.00.
- o) On or about April 14, 2009, defendant **EDWARD MANOOKIAN** caused a wire transfer of \$2,650.00 to be sent from a Bank of America account in the name of Manning Associates, Inc, d/b/a Melanocorp, Inc., to an account in the name of GL Biochen.

All in violation of Title 18, United States Code, Section 371.

COUNT TWO

THE GRAND JURY FURTHER CHARGES:

1. The allegations in Paragraphs 1 through 31 of Count One of this Indictment are hereby incorporated and realleged as if fully set forth herein.
2. Between on or about September 17, 2007 and continuing through in or around April 2009, in the Middle District of Tennessee and elsewhere, defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, and KAREN MANOOKIAN** did willfully,

knowingly and unlawfully combine, conspire, confederate, and agree with each other, and with other persons who are known and unknown to the Grand Jury, to defraud the United States or one of its agencies or departments, in particular, the U.S. Food and Drug Administration, for the purpose of impeding, impairing, obstructing, and defeating its lawful functions.

Overt Acts

3. In furtherance of this conspiracy, and to accomplish its purposes and objects, defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, KAREN MANOOKIAN** and other conspirators committed and caused to be committed, in the Middle District of Tennessee, and elsewhere, at least one of the following overt acts, among others:

- a) On or about September 17, 2007, defendants **EDWARD MANOOKIAN** and **BRIAN MANOOKIAN** caused a letter to be sent to FDA stating that Melanocorp had stopped all promotion and sale of MII in the United States and had stopped taking orders for MII from United States residents. In this letter, defendant **EDWARD MANOOKIAN** stated that Melanocorp "will not accept orders for Melanotan II from any individual with a U.S. mailing address" and that Melanocorp "has stopped taking orders for Melanotan II from U.S. residents."
- b) On or about December 14, 2007, defendant **EDWARD MANOOKIAN** caused a letter to be sent to FDA from his attorney confirming that Melanocorp had stopped taking orders for MII from U.S. residents. This letter also states that "Melanocorp does not disagree that FDA considers Melanotan II to be an unapproved new drug and that FDA has requested that Melanocorp not distribute or market the product in the United States."

- c) On or about February 6, 2009, defendant **KAREN MANOOKIAN** caused a package containing MII to be sent to an address in Seal Beach, California via United Parcel Service.
- d) On or about February 9, 2009, defendants **EDWARD MANOOKIAN** and **KAREN MANOOKIAN** caused a package containing MII to be sent to an address in Long Beach, California via United Parcel Service in fulfilment of a customer order.
- e) On or about February 12, 2009, defendants **BRIAN MANOOKIAN** and **KAREN MANOOKIAN** caused a package containing MII to be sent to an address in Gainesville, Florida via United Parcel Service.

All in violation of Title 18, United States Code, Section 371.

COUNT THREE

THE GRAND JURY FURTHER CHARGES:

- 1. The allegations in Paragraphs 1 through 31 of Count One and Paragraphs 1 through 3 of Count Two hereby incorporated and realleged as if fully set forth herein.
- 2. On or about February 11, 2009, defendant **KAREN MANOOKIAN**, with the intent to defraud and mislead, caused to be introduced and delivered for introduction into interstate commerce, from the Middle District of Tennessee to Long Beach, California, one vial of MII, an unapproved new drug,

In violation of Title 21 United States Code, Sections 331(d), 333(a)(2), and 355.

COUNTS FOUR THROUGH SIX

THE GRAND JURY FURTHER CHARGES:

1. The allegations in Paragraphs 1 through 31 of Count One and Paragraphs 1 through 3 of Count Two hereby incorporated and realleged as if fully set forth herein.

The Scheme to Defraud

2. Beginning in or around July 2006 and continuing until in or around April 2009, defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, and KAREN MANOOKIAN** devised and intended to devise a scheme and artifice to defraud and to obtain money by means of materially false and fraudulent pretenses, representations, and promises, and for the purpose of executing such scheme and attempting so to do, caused packages to be deposited to be sent or delivered by a private and commercial interstate carrier and to be delivered by mail or by any private or commercial interstate according to the direction thereon, which scheme is further described in the following paragraphs.

3. It was part of the scheme that defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, and KAREN MANOOKIAN** caused representations to be made to Melanocorp customers and potential Melanocorp customers that the MII sold by Melanocorp was manufactured in the United States.

4. It was further part of the scheme that defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, and KAREN MANOOKIAN** caused the Melancorp website to advertise that MII offered by Melanocorp was made in the United States.

5. It was further part of the scheme that defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, and KAREN MANOOKIAN** caused Melanocorp to promote the MII

sold by Melanocorp by distinguishing it from Chinese-made MII purportedly sold by competitors.

6. It was further part of the scheme that defendants **EDWARD MANOOKIAN**, **BRIAN MANOOKIAN**, and **KAREN MANOOKIAN** caused Melanocorp to acquire MII manufactured in China.

7. It was further part of the scheme that defendants **EDWARD MANOOKIAN**, **BRIAN MANOOKIAN**, and **KAREN MANOOKIAN** caused MII that had been manufactured in China to be sold and distributed to customers of Melanocorp, despite the representations that Melanocorp only offered MII that had been manufactured in the United States.

8. It was further part of the scheme that defendants **EDWARD MANOOKIAN**, **BRIAN MANOOKIAN**, and **KAREN MANOOKIAN** caused representations to be made to Melanocorp customers and potential Melanocorp customers that Melanocorp had never had a shipment of MII held by customs officials of certain countries, including Australia, despite knowing at the time that the relevant customs agencies had seized shipments of MII sent by Melanocorp.

9. It was further part of the scheme that defendants **EDWARD MANOOKIAN**, **BRIAN MANOOKIAN**, and **KAREN MANOOKIAN** caused representations to be made to Melanocorp customers and potential Melanocorp customers that MII sold by Melanocorp was meant for human consumption, despite Melanocorp having being informed by manufacturers and laboratories from which it acquired MII that this MII was for research only or was not for human use or therapeutic use.

The Mailings

10. On or about the dates set forth below, in the Middle District of Tennessee and elsewhere, defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, and KAREN MANOOKIAN**, for the purpose of executing the scheme, and attempting to do so, did knowingly cause the following packages to be deposited to be sent and delivered by a private and commercial interstate carrier and to be delivered by mail or by any private or commercial interstate carrier according to the direction thereon, each being a separate count of this Indictment:

Count	Date	Description of Package
4	1/29/2009	Package containing MII, shipped via United Parcel Service from the Middle District of Tennessee to an address in Glasgow, UK
5	2/19/2009	Package containing MII, shipped via United Parcel Service from the Middle District of Tennessee to an address in Lower Templestowe, Australia
6	4/3/2009	Package containing MII, shipped via United Parcel Service from the Middle District of Tennessee to an address in Athens, Greece

All in violation of Title 18, United States Code, Sections 1341 and 2.

FORFEITURE ALLEGATIONS

1. The preceding allegations of this Indictment are incorporated by reference as if fully set forth herein.

2. Upon conviction of an offense alleged in Counts Four through Six, defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, and KAREN MANOOKIAN**, joint and severally, shall forfeit to the United States of America pursuant to Title 18, United States Code, Section 981(a)(1)(c) and 28 United States Code, Section 2461, any property which constitutes or is derived from proceeds traceable to the scheme and artifice to defraud in each offense, including but not limited to a money judgment in an amount to be determined, said amount representing the amount of proceeds obtained as a result of such offense.

3. If any of the property described above, as a result of any act or omission of defendants **EDWARD MANOOKIAN, BRIAN MANOOKIAN, and KAREN MANOOKIAN:**

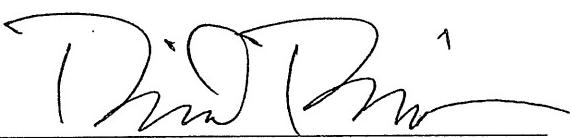
- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property that cannot be divided without difficulty,

the United States shall be entitled to forfeiture of substitute property, and it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any

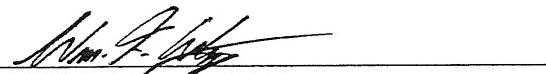
other property of defendants **EDWARD MANOOKIAN**, **BRIAN MANOOKIAN**, and
KAREN MANOOKIAN up to the value of said property listed above as subject to forfeiture.

A TRUE BILL


FOREPERSON


DAVID RIVERA

UNITED STATES ATTORNEY


WILLIAM F. ABELY

ASSISTANT UNITED STATES ATTORNEY